4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2011-M-0735, FDA-2011-M-0736, FDA-2011-M-0737, FDA-2011-M-0746, FDA-2011-M-0786, FDA-2011-M-0791, FDA-2011-M-0792, FDA-2011-M-0796, FDA-2011-M-0832, FDA-2011-M-0837, FDA-2011-M-0848, FDA-2011-M-0865, FDA-2011-M-0866, FDA-2011-M-0910, and FDA-2011-M-0917]

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the Agency's Division of Dockets Management.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness data to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 of this document when submitting a written request. See the SUPPLEMENTARY INFORMATION section for electronic access to the summaries of safety and effectiveness.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the FD&C Act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from October 1, 2011, through December 31, 2011. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

Table 1.--List of Safety and Effectiveness Summaries for Approved PMAs Made Available From October 1, 2011, Through December 31, 2011

PMA No., Docket No.	Applicant	Trade Name	Approval Date
P110003, FDA-2011-M-0746	Pluromed, Inc.	LEGOO	September 28, 2011
P090024, FDA-2011-M-0737	Siemens Healthcare Diagnostics	ADVIA CENTAUR HBEAG assay and quality control material	October 11, 2011
P040024 (S51), FDA-2011-M-0735	Medicis Aesthetics, Inc.	RESTYLANE injectable gel	October 11, 2011
P010029 (S8), FDA-2011-M-0736	Ferring Pharmaceuticals, Inc.	EUFLEXXA (1% sodium hyaluronate)	October 11, 2011
P110022, FDA-2011-M-0786	Roche Diagnostics Corp.	ELECSYS anti-HBC IGM immunoassay and ELECSYS PRECICONTROL anti-HBC IGM	October 26, 2011
P110011, FDA-2011-M-0791	Medtronic Ireland	ASSURANT COBALT iliac balloon-expandable stent system	October 26, 2011
P100042, FDA-2011-M-0792	Gen-Probe Incorporated	APTIMA HPV assay	October 28, 2011
P110019, FDA-2011-M-0796	Abbott Vascular	XIENCE PRIME and XIENCE PRIME LL EVEROLIMUS-eluting coronary stent system	November 1, 2011
P100041, FDA-2011-M-0837	Edwards Lifesciences, LLC	EDWARDS SAPIEN transcatheter heart valve and RETROFLEX 3 delivery system, RETROFLEX balloon catheter and crimper	November 2, 2011
P090016, FDA-2011-M-0832	Merz Aesthetics, Inc.	BELOTERO balance	November 14, 2011
H090002, FDA-2011-M-0848	BSD Medical Corp.	BSD-2000 hyperthermia system	November 18, 2011
P110010, FDA-2011-M-0865	Boston Scientific Corp.	PROMUS ELEMENT PLUS EVEROLIMUS-eluting platinum chromium coronary stent system	November 22, 2011
P100024, FDA-2011-M-0866	Dako Denmark A/S	HER2 CISH PHARMDX kit	November 30, 2011
P110025, FDA-2011-M-0917	Roche Diagnostics Corp.	ELECSYS anti-HBC IGM immunoassay and ELECSYS PRECICONTROL anti-HBC IGM for use on the MODULAR ANALYTICS E170 immunoassay analyze	December 14, 2011
P100046, FDA-2011-M-0910	AtriCure Inc.	ATRICURE SYNERGY ablation system	December 14, 2011

II. Electronic Access

Persons with access to the Internet may obtain the documents at http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm and http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/HDEApprovals/ucm161827.htm.

Dated: March 12, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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